

APR -4 1997 K965233

revised 4/9

### 510(k) Summary

**1.0 Date Prepared**  
December 23, 1996

**2.0 Submitter (Contact)**  
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**3.0 Device Name**  
Proprietary Name: SHARPSITE Ac  
  
Common Name(s): Rigid Rod Lens Endoscopes  
  
Classification Name: Endoscope, rigid  
Nasopharyngoscope (flexible or rigid)

**5.0 Device Classification**  
Endoscope, rigid      Procode 78GCM      Class II ; 21 CFR 876.1500      Tier 2  
Nasopharyngoscope      Procode 77EOB      Class II ; 21 CFR 874.4760      Tier 2  
(flexible or rigid)

**6.0 Device Description**  
The SHARPSITE Ac endoscopes are a series of small diameter, rigid rod lens endoscopes; available in diameters of 2.7mm, 4.0mm and 5.0mm with tip angles of 0, 30 and 70 degrees. The length of the scopes range from 175mm to 188 mm. Each scope is fitted with a removable light port adapter for use with light cables from different manufacturers.

**7.0 Intended Use**  
The Xomed SHARPSITE Ac rigid rod lens endoscopes are intended for use in surgical imaging in otolaryngology and Head and Neck procedures, including rhinology, and endoscopic plastic and reconstructive surgery.

**8.0 Substantial Equivalence**  
Substantial equivalency is based on the fact that the SHARPSITE Ac endoscopes are equivalent to current Xomed endoscopes in their intended use and materials. They are likewise equivalent in design, intended use and performance claims to sinuscope currently marketed by Smith & Nephew (S&N) ENT.